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REMARKS

In the Office Action dated August 11, 2006, the Examiner has rejected claims 1-39 over U.S. Patent 4,905,679 to Morgan in view of U.S. Patent 4,512,038 to Alexander et al., and further in view of one or more of U.S. Patent 6,293,949 to Justis et al., U.S. Patent 6,206,882 to Cohen, U.S. Patent 4,887,595 to Heinig, and U.S. Patent 4,743,260 to Burton, as further discussed below. Applicants believe that the analysis and response presented herein shows that the claims are in condition for allowance. In view of the following remarks, reconsideration and allowance of the pending claims are respectfully requested.

Allowable Subject Matter

Claims 33 and 34 were objected to in the Office Action as being dependent upon a rejected base claim, but included allowable subject matter. Applicants thank the Examiner for this indication of allowable subject matter, and notes that the subject matter of allowable claims 33 and 34 has been incorporated into new claims 47 and 48.

The rejections under 35 U.S.C. § 103

Claims 1-4, 6-19, 22-23 and 38-39 were rejected under 35 U.S.C. §103(a) as being allegedly obvious over U.S. Patent No. 4,905,679 to Morgan in view of U.S. Patent No. 4,512,038 to Alexander et al. Regarding independent claim 1, Applicants submit that a *prima facie* case of obviousness cannot be established because there is no teaching, suggestion, or motivation to arrive at the combination of features recited in claim 1, and for other reasons. As further discussed below, the withdrawal of this rejection is respectfully requested.

The Office Action alleges that Morgan discloses “an orthopedic device (Fig. 3) for the fixation of two or more bone portions, an elongate member (14) that has bends that are capable of allowing the bone portions to at least move with translational movement with respect to one another” [emphasis added]. However, the “bends” in Morgan are a result of having bent the material in leg section 14 past its yield point. Thus, the Morgan “bends” do not enable movement of the bone portions; rather, they are a result of having bent leg section 14 thereby moving the bone portions. These “bends” are designed to prevent bone movement, as the whole plate holds broken bones together. Indeed, the Office Action recognized that disclosure, noting that “Morgan is capable of performing the method of fixedly attaching the device to two or more bone portions” (see p. 3 of the Office Action [emphasis added]). Morgan is indeed directed to fixedly attaching the device and does not permit for further translational or rotational movements of the bone portions.

Respectfully, the Morgan and Alexander reference cannot be properly combined because each is directed to distinct and mutually exclusive techniques of repairing bone fractures. Morgan discloses a plate-like device that is attached to bone fragments and then is kinked or twisted in the middle to exert force on the fragments to keep them together. Morgan does not disclose sharing the load with anything other than the plate-like device and, rather, discloses stress shielding the bone fragments. The Alexander reference, on the other hand, discloses a gradual shifting of stress from the bio-absorbable composite tissue scaffold to new tissue. In particular, the Alexander reference discloses a biodegradable substance that can be made into artificial ligaments or bone plates, which initially receive substantially all of the stress on the affected area, but gradually degrade to transfer stress to the bone tissue itself. Applicants do not see a proper motivation to combine the references wherein the purpose of one reference is to

maintain force on an implant (Morgan) and the purpose for the other reference is the gradual shifting of stress from an implant to a bone (Anderson). If such a combination were made as alleged in the Office Action it would defeat the purposes of both. Applicants submit, therefore, that the combination of Morgan and Alexander against the present claims is not obvious.

Applicants also submit that a *prima facie* case of obviousness cannot be established because there is no teaching, suggestion, or motivation to arrive at the combination of features recited in claim 1. In the present case, there is no information in the Morgan or Alexander references that would teach, motivate, or suggest to one of ordinary skill in the art to combine the references as the Office Action proposes. The Office Action suggests that a motivation to combine Morgan with Alexander is "to better allow the device to gradually translate support to the bone plate or orthopedic device in view of Alexander et al. to better allow the bone portions to heal at their natural rate." No such statement can be found in the references, and it is believed that no such suggestion can be construed either. The Morgan reference fails to mention any kind of bio-absorbable materials. For its part, Alexander discloses only making implants out of its disclosed material, but does not suggest covering existing implants in it, and doing so runs counter to its teachings of transferring stress from implant to tissue. No statements can be found in either reference that teach, suggest, or modify the combination of them both.

The only motivation to combine the reference comes not from the references themselves, but only from the present application, or perhaps from facts within the personal knowledge of the Examiner. If the Office Action indeed relies on personal knowledge of the Examiner, Applicants hereby request an affidavit of the Examiner, pursuant to 37 C.F.R. § 1.104(d)(2), to specifically describe such personal knowledge in order to better develop a full record on which the prosecution can advance.

For all of the foregoing reasons, Applicants respectfully request withdrawal of the rejection of claim 1 over Morgan and Alexander. Claims 2-4, 6-19, 22-23 and 38-39 depend from claim 1, and thus their rejection over Morgan and Alexander should also be withdrawn for at least the reasons recited above with respect to claim 1.

Claim 5 was rejected under 35 U.S.C. §103(a) as being allegedly obvious over the combination of U.S. Patent No. 4,905,679 to Morgan and U.S. Patent No. 4,512,038 to Alexander et al. as applied to claim 1 above, and further in view of U.S. Patent No. 6,293,949 to Justis et al. Regarding claim 5, Applicants submit that a prima facie case of obviousness cannot be established because there is no proper teaching, suggestion, or motivation to arrive at the combination of features in claim 5. The Office Action provides only conclusory statements of generalized advantages, alleging that it would have been obvious to combine the references "to better arrange the orthopedic device onto the bones." Such conclusory statements do not meet the Office's burden to establish motivation and desirability. See, e.g., MPEP 2142. Moreover, none of the Morgan, Alexander, or Justis references appear to disclose the motivation alleged in the Office Action, and no citation is provided that identifies where such motivation can be found. The Justis reference discloses only that "plate 200 may be pre-stressed prior to being secured to the upper and lower vertebrae . . . , thus initially transforming a portion of the SMA material from austenite into SIM." Justis, col. 11, lines 33-37. It will be appreciated that Justis discloses the fact that plate 200 simply may be deformed; whether plate 200 may be used "to better arrange the orthopedic device onto the bones" does not appear in Justis. Whether something can be deformed (Justis) is not the same as why it should be deformed (rationale in the Office Action). Respectfully, the motivation relied on by the Office Action is nowhere to be found in the references.

It appears, therefore, that the combination proposed against claim 5 is motivated only by the present application, or possibly relies on facts within the personal knowledge of the Examiner. If the Office Action indeed relies on such personal knowledge, Applicants request an affidavit of the Examiner, pursuant to 37 C.F.R. § 1.104(d)(2), to specifically describe such personal knowledge in order to better develop a full record on which the prosecution can advance. For all of the foregoing reasons, Applicants respectfully request withdrawal of the rejection of claim 5 over Morgan, Alexander, and Justis.

Claims 20-21 are rejected under 35 U.S.C. § 103(a) as being allegedly obvious over the combination of U.S. Patent No. 4,905,679 to Morgan and U.S. Patent No. 4,512,038 to Alexander et al. as applied to claim 19 above, and further in view of U.S. Patent No. 6,206,882 to Cohen. A *prima facie* case of obviousness cannot be established because there is no teaching, suggestion, or motivation to arrive at the combination of features recited in claim 20, and as noted above, conclusory statements without factual support from the references cannot suffice. Cohen discloses slots cut into bone plate 10, wherein the flexure slots "enhance the elasticity or flexibility of the device during a surgical procedure" (see col. 3, lines 42-43 [emphasis added]). Cohen further states that "[t]his characteristic enables a surgeon to easily conform the plate body to the contours of the spinal vertebrae without the need for extraneous surgical instrumentation" (see col. 3, lines 43-46 [emphasis added]). In short, Cohen discloses slots useful for bending a plate during surgery, not for permitting translational or rotational movement after implantation. In the instant application, devices are disclosed that "[a]fter a selected period of time or under certain conditions, the amount and nature of the support/fixation can vary to facilitate a desirable treatment. For example, the variable or dynamizable support develops new, strong bone tissue minimizing the risk of pseudoarthrodesis." Paragraph 0026. As will be understood, the instant

application is directed to providing some degree of flexibility during post-operative recovery and rehabilitation. Cohen does not teach or suggest to a person of ordinary skill in the art to create slots in a bone plate so that "[a]fter a selected period of time or under certain conditions, the amount and nature of the support/fixation can vary to facilitate a desirable treatment." Rather, Cohen confines use of the slots, and more particularly the flexibility provided by the slots, to the surgical procedure, not to post-operative rehabilitation. As such, there is no suggestion, motivation, or teaching to combine the disclosure of Cohen with Alexander and Morgan.

Additionally, claim 21 is allowable on its own merit because the cited references fail to disclose a reinforcing component disposed in the plurality of voids. Claim 21, therefore, is allowable over the cited references for at least the reasons cited above. Applicants respectfully request withdrawal of the rejection of claims 20 and 21.

Claims 24-32 and 36-37 are rejected under 35 U.S.C. §103(a) as being allegedly obvious over the combination of U.S. Patent No. 4,905,679 to Morgan and U.S. Patent No. 4,512,038 to Alexander et al. as applied to claim 1 above, and further in view of U.S. Patent No. 4,887,595 to Heinig et al.

In addition to the facts noted above with respect to claim 1, a *prima facie* case of obviousness for claims 24-32 and 36-37 cannot be established because there is no teaching, suggestion, or motivation to arrive at the combination of features recited in them, as will be discussed below. Specifically, there is no information in the Morgan, Alexander, or Heinig references (or otherwise of record) that would motivate one of ordinary skill in this art to combine those references, or show the combination's desirability, as the Office Action proposes. The Office Action suggests that a motivation to combine the three references is "to better secure the spinal area in use." With due respect, that language only appears in the Heinig reference

with regard to the location of "fasteners 82" and whether the fasteners are located on the "inside of rod portion 24" or the "outside of rod portion 24." Col. 5, lines 4-9. Whether fasteners 82 of the Heinig reference are located on the inside or outside of rod portion 24 is of no consequence to producing the device alleged in the Office Action. Furthermore, the language in Heinig is not directed to, and certainly does not suggest constructing the device as suggested in the Office Action, by combining Morgan and Alexander to produce "an elongate member that is an orthopedic rod that may be a spinal rod, that has a plurality of voids, and that is capable of being deformed." Claims 24-32 and 36-37, therefore, are not shown or suggested in the combination of Morgan, Alexander, Heinig, or Burton. Claims 24-32 and 36-37 are allowable in view of the references cited of record. Withdrawal of the rejection is respectfully requested.

Claim 35 is rejected under 35 U.S.C. §103(a) as being allegedly obvious over the combination of U.S. Patent No. 4,905,679 to Morgan and U.S. Patent No. 4,512,038 to Alexander et al. and U.S. Patent No. 4,887,595 to Heinig et al. as applied to claim 24 above, and further in view of U.S. Patent No. 4,743,260 to Burton.

In addition to the facts noted above regarding claim 1, a *prima facie* case of obviousness cannot be established for claim 35 because there is no teaching, suggestion, or motivation to arrive at the combination of features recited in it. Specifically, there is no information in the Morgan, Alexander, Heinig, or Burton references (or otherwise of record) that would motivate one of ordinary skill in this art to combine those references, or would show the desirability of the combination, as the Office Action proposes. The Office Action suggests that a motivation to combine the three references is "to better secure and structure the spinal area in use." With due respect, only part of that language appears in only one reference, Heinig, and even then it is with respect to the location of "fasteners 82" and whether the fasteners are located on the "inside of

rod portion 24” or the “outside of rod portion 24.” Col. 5, lines 4-9. Whether fasteners 82 of the Heinig reference are located on the inside or outside of rod portion 24 is of no consequence to producing the device alleged in the Office Action. Furthermore, the language in Heinig is not directed to, and certainly does not suggest constructing the device, as suggested in the Office Action, by combining Morgan, Alexander, and Burton to produce “a device . . . having at least a hollow interior lumen for reinforcing material.” Claim 35, therefore, is not shown or suggested in the combination of Morgan, Alexander, Heinig, or Burton. Claim 35 is allowable in view of the references cited of record. Withdrawal of the rejection is respectfully requested.

The combination of references also fails to recite all elements of claim 35, thus failing the requirement for obviousness that all claim limitations must be taught or suggested. The Office Action is respectfully incorrect to suggest that Burton discloses “a rod with a hollow interior (18a) that may have a reinforcing material inside for support.” The cited portion of the Burton reference (col. 4, lines 21-27) has been reviewed, but no indication that it discloses a rod with a hollow interior appears. Rather, Burton discloses “[i]nternal reinforcement with dissimilar polymers or filaments provide increased strength over that of a single phase plastic . . . . [I]t is preferred that internal fibers be used for reinforcement.” Applicants note that although Figs. 1, 10, and 11 show circular drawing detail at the end of the rods, the circular detail does not depict a “hollow interior” as alleged, let alone an “interior lumen” as recited by claim 35, but instead “filaments” formed in the overall device that “provide increased strength over that of a single phase plastic.” None of the Morgan, Alexander, Heinig, or Burton references disclose an “interior lumen,” and thus all elements of claim 35 are not shown.

No amendments have been made to narrow any of the claims, and no narrowing is intended by any aspect of this response to Office Action. Previously withdrawn claims 40-46



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have been cancelled without prejudice to refiling in this or a continuing application. Claims 33 and 34 have been cancelled without prejudice, since their subject matter has been incorporated into new claims 47 and 48. New claims 49-62 have been added that depend from claims 47 or 48. These new claims generally track subject matter in previously-filed claims. No new matter has been added.

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action but are simply provided to address the rejections made in the Office Action in the most expedient fashion. Applicants reserve the right to contest later positions taken by the Examiner that are not specifically addressed herein.

#### Conclusion

Reconsideration in view of the above remarks is respectfully requested. All claims are allowable, and a Notice of Allowance is respectfully requested. Should it be determined that any further action is necessary to place this application in better form for allowance, or for appeal should that become necessary, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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Pg. 19 of 19